EC- Declaration of Conformity

We, **LDBIO DIAGNOSTICS,** 19A rue Louis Loucheur, 69009 Lyon, France, hereby confirm that we have installed a quality management system according to the harmonized standards ISO 9001:2008 and NF EN ISO 13485:2004. Our quality management system has been certified for compliance with said standards by the independent bodies LNE/GEMED 0459 (certification N°9742 rev. 3, valid until July 20th, 2015).
Compliance with additional requirements of annex IV (directive 98/79 EC) for products classified as either annex II list B has been certified by the LNE/GMED (certification 9760 rev. 2, valid until July 20th, 2015).

We further confirm that the IVD products listed in attachment 1 are designed, manufactured and controlled by us in accordance with the European directive 98/79 EC and that they meet the essential requirements according to annex I of said directive. Applicable conformity assessment procedures according to annex III or annex IV, whatever applicable, of said directive have been completed for these products.

With the CE mark on the listed products we declare that the products are in conformity with the applicable directive 98/79/EC and harmonized standards.

LDBIO DIAGNOSTICS

Denis Limonne
Managing director

Denis Limonne
2012.10.10
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APPROUVÉ

Attachments

Product name	Reference name	Class
Toxoplasma WB IgG-IgM	TOP-WB12GM, TOP-WB24GM, TOP-WB96GM	Test listed in annex II, List B
Toxocara WB IgG	TXA-WB12G, TXA-WB24G, TXA-96G	
Leishmania WB IgG	LES-WB12G, LES-WB24G, LES-WB96G	
Echinococcus WB IgG	ECH-WB12G, ECH-WB24G, ECH-WB96G	
Cysticercosis WB IgG	CYS-WB12G, CYS-WB24G, CYS-WB96G	
Schistosoma WB IgG	CYS-WB12G, CYS-WB24G, CYS-WB96G	
Trichinella WB IgG	TRI-WB12G, TRI-WB24G, TRI-WB96G	
Fasciola WB IgG	FAS-WB12G, FAS-WB24G, FAS-WB96G	
LDBIO TOXO II IgG	TOXO II 12G, TOXO II 24G, TOXO II 96G	Test listed in annex II, List B